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Description

The invention relates to a method for producing endoprostheses, in particular individually constructed implants and augments for reconstructive head surgery, in which the data set of a three-dimensional actual model of the existing bone structure of a patient is acquired by means of computer tomography, the actual model thus determined is subtracted in a computer from the data set of an existing or computer tomographically acquired three-dimensional reference model, and a computer-internal model is formed for the endoprosthesis from the difference of the data sets, which model is adapted on the video screen of the computer to the special anatomical features of the patient by an interactive manipulation of the data, and the data set thereof is finally used for the computer-controlled manufacture of the endoprosthesis.

Similar methods which, however, do not comprise any corrective adaptation to the special anatomical features of the patient by an interactive manipulation of the data set, are known, for example from EP 0 255 797 B1; EP 0 093 869 A1; EP 0 146 491 A2; or EP 0 097 001 A1. In connection with the methods known according to this prior art, it is possible with the use of suitable methods generating high-resolution images to adapt such endoprostheses relatively accurately to the existing bone structure of the patient to be supplemented.

However, in the manufacture of endoprostheses for restoring or for filling up bone defects in the region of the facial or brain skull, in particular in the manufacture of augments for supplementing atrophied alveolar processes for making available a suitable base for dental prostheses, an exact adaptation of the surface of abutment of the endoprosthesis on the surface of the still-existing bone structure

to be supplemented does not suffice. Even with a highly exact adaptation of the endoprosthesis to the existing surface, painful pressure phenomena occur, for example in the region of the exit points of the bone canals receiving the nerves, or, in the case of progressed atrophy, within the region of the exposed bone canals.

For this reason, the surface of the endoprosthesis has to be shaped within the region of contact with nerval structures in a manner deviating from the directly derived geometric form, by recessing the surface within this region of the surface. In this case, the recessed surface areas have to change to the adjacent, not recessed surface areas with softly rounded transitions, with the endoprosthesis being supported in these non-recessed areas on the existing bone structure.

A similar corrective adaptation of the endoprosthesis to special anatomical features of the existing bone structure is required if the surfaces of the existing bone structure and those of the endoprosthesis coming into contact with one another have undercuts and/or projections which, when the endoprosthesis it put into place, are in the way. Such undercuts and/or projections interfering with the surgical intervention have to be eliminated prior to surgery as well, by adapting the endoprosthesis.

Finally, recesses in the endoprostheses to be manufactured are also required within the region of other non-osseous anatomical structures of the head, for example within the region of the nasal cavities or eye sockets, the lateral nasal cavities, the auditory meatus, the middle or inner ear, as well as of the base of the skull, and particularly of the endocranium.

According to the prior art, the corrective adaptations and recesses on endoprostheses explained above are possible only by highly labour-intensive, manual after-working, for example by carving or milling. Such after-working by

hand requires much experience and sensitivity and leads to non-usability of the endoprosthesis if the adaptations are faulty.

A method for producing a hip joint prosthesis, which is insertable in the femur, is known from EP 0 093 869 A1, in which the adaptation of the contours of the endoprosthesis to the special anatomical features of the patient is carried out on the screen of the computer by means of a covering pen or an electronic writing pen. The data representing the individual layer images of the endoprosthesis are changed (manipulated) accordingly and stored with these aids. Based on the stored data of the layer images manipulated in this way, the computer is then capable of computing the data set for a three-dimensional model. In the manufacture of the endoprosthesis, the prosthesis manufacturing machine is then controlled on the basis of this data set.

The computer-assisted construction and adaptation of endoprostheses known according to this prior art is highly labour-intensive and complicated and permits at best only a rough adaptation of the endoprosthesis to the bone structures existing on the part of the patient. Such rough adaptation is entirely sufficient, for example, for orthopaedic hip joint prostheses because there, the outer surface of the prosthesis coming to rest against the inside wall of the hollow space of the bone, such space having been created artificially by scraping out spongiosa, is provided with steps, which are intended in order to effect an enhanced introduction of the static and dynamic forces into the bone. For said reason, the contours of the steps there in the successive horizontal planes need to be only approximately adapted to the curve of the borderline surface between spongy and compact matter.

As opposed to orthopaedic prostheses, with endoprostheses for head surgery, the introduction of static and dynamic forces matters less than a corrective adaptation of the curves of the surface, leaving free sensitive nerval structures of the surface of the bone. Simple layer representation and manually made

changes in the contours of the individual layer images no longer suffice with such corrective adaptation. Particularly if the contours of the individual sectional lines were corrected layer by layer, it would be extremely difficult to allow the recessed surface areas to change with softly rounded transitions to the adjacent, unrecessed surface areas, where the endoprosthesis is supported on the existing bone structure.

Therefore, the object of the invention is to further develop the method of the type mentioned at the outset in such a way such that the expenditure of labour required for the corrective adaptation of the surfaces of the endoprosthesis is reduced, and provision is automatically made for softly rounded transitions between the recessed surface areas and the adjacent, non-recessed surface areas.

To achieve this object, the invention proposes, on the basis of the method of the type mentioned at the outset, that the data sets of the actual model and of the reference model are converted into the data of a CAD free-form surface geometry describing the limiting surfaces of the models through spline and Bezier functions oriented to points of support, and are represented on the video screen of the computer arranged one on top of the other, and that, with the aid of this imaging, part areas of the interface of the actual model are recessed by displacing points of support in the direction of the volume of the reference model.

The hollow spaces formed through computer technology by displacing part areas of the interface of the actual model are cleared from the volume of the reference model in the mechanical manufacture of the bone implant. In the later implantation of the augment, these hollow spaces thus are at exactly the sites where the adaptation was made.

The method according to the invention has the advantage that the expenditure of labour for the corrective adaptation is extraordinarily low even in connection with

highly complicated structures, and that in each adaptation process, the areas of transition between the recessed surface areas and the non-recessed surface areas are to a certain extent automatically softly rounded.

This has to be attributed to the fact that in the method according to the invention, the limiting surfaces of the models are represented in a free-form surface geometry, in which the surfaces are described by Spline and Bezier functions oriented on points of support. Thus, the limiting surfaces to a certain extent become coherent, spatial structures, the manipulations of which carried out locally at points of support have effects on all surfaces adjoining this point of support, whereby provision is automatically made that the surface areas changed by the point-of-support displacement change continuously and softly rounded to the adjacent, non-recessed surface areas.

Especially the creation of such soft transitions is extremely important in connection with endoprostheses for head surgery, and can be accomplished only poorly and laboriously with the measures known for this purpose according to the prior art.

The final shaping and fine adaptation of the new interface curve formed by the recession is expediently supported by reflection, expanding, turning or smoothing. These manipulation functions make it possible to also finally finely adapt the prosthesis to the computer-internal model already in the computer, so that also the fine adaptations are already taken into account in the manufacture of the prosthesis.

The method according to the invention is particularly suitable for the manufacture of implants or augments in oral surgery. However, it can also be applied for other sensitive regions of bone construction, for example for the construction of individual implants of parts of the skull for eliminating osseous continuity defects following temporoparietal trepanation.

In particular, the method according to the invention has the advantage that the endoprosthesis can be directly produced with all special features to be taken into account. After-working or manual fine adaptation is no longer required. Another advantage consists in that the treatment time during the surgical intervention can be clearly reduced.

Additional advantages are obtained if a high-resolution computer tomograph with helical data collection is used for the data acquisition. In this image-generating method, the part of the body of the patient to be detected in terms of data is detected by a helical spiral, the pitch of which is predetermined by the feed of the table per revolution of the X-ray tube.

The entire patient volume detected by the spiral can be subsequently reconstructed again layer by layer in accordance with conventional computer tomographical representation, whereby the spacing of these reconstructed layers is not predetermined by the pitch of the spiral, but, for example, can also be selected smaller.

In view of the method of the type specified at the outset, in which the exactness of the geometric adaptation of the endoprosthesis to the bone structure of the patient is limited only by the validity of the processed computer tomographical data, two important indispensable advantages are obtained through the use of such a computer tomograph as compared to other computer tomographical acquisition methods:

1. The rapidity of the data recording of about 20 seconds, i.e., quasi during one single breathhold, assures a minimising of artefacts of motion on the part of the patient, which could be recognised and corrected only with difficulty in the subsequent reconstruction process.

2. The detection of a volume instead of individual surfaces (layers) permits the computer-internal reconstruction of a geometric model combined with the best possible detection of intermediate later regions; as opposed to conventional computer tomographical techniques, a complete loss of information is avoided, or a loss of information increasing in the central direction is avoided in the case of adjoining or overlapping layer expanses in connection with a geometrically virtually biconcave bundle of X-rays.

An embodiment of the method according to the invention is described in greater detail below with reference to the drawings, in which:

Fig. 1 schematically shows in a block diagram the method steps of the method according to the invention;

Fig. 2 shows an equipment configuration for carrying out the method according to the invention;

Fig. 3 shows the idealised free-form surface geometry of an atrophied lower jaw as an actual model shown by a perspective view;

Fig. 4 shows the idealised free-form surface geometry of a comparative model shown as the reference model in a perspective view;

Fig. 5 shows the presentation of the superimposition of Figs. 3 and 4 on the screen; and

Fig. 6 shows the representation of a vertical section along line A--A in Fig. 5.

Fig. 1 schematically shows the sequence of the method for producing an endoprosthesis according to the invention. In method step A1, the data set of the actual model is first acquired computer tomographically on the lower jaw of the

patient to be treated. At the same time, the data set of the reference model is made available at position A2. This data set is available either in a suitable storage medium or it is also acquired computer tomographically from a physically existing reference model.

In method step B, the data sets of the actual model and of the reference model are converted by computer into the data unit CAD free-form surface geometry, which is a three-dimensional representation of the limiting surfaces of the models which is oriented to points of support, such limiting surfaces being described by numerical Spline and Bezier functions. The surface structures in this representation are characterised in that they can be easily handled by interactive CAD modelling and manipulating methods.

In the subsequent method step C, the converted data sets of the actual model and of the reference model are shown superimposed on the video screen. Based on this image, part areas of the interface of the actual model are displaced by an interactive CAD modelling and manipulating method in the direction of the volume of the reference model. Recesses and hollow spaces are produced in this way in the regions of the endoprosthesis where no contact is desired with the existing bone structure. Likewise, projections and/or undercuts of the endoprosthesis to be produced can be removed, which can be seen in advance to pose problems when the endoprosthesis is inserted.

Finally, in method step D, the difference of the data of the actual and reference models is formed, and a data set is generated in this way which can serve as the model for the computer-assisted manufacture of the endoprosthesis.

Based on this data set, the finished endoprosthesis is finally produced in method step E with the aid of a computer-controlled manufacturing unit.

The equipment configuration shown in Fig. 2 has a computer tomograph 1 with helical data acquisition. This computer tomograph is used for acquiring the data of the actual model on the patient. The data of the reference model are either acquired in the computer tomograph 1 on the basis of a physically existing reference model as well, or such data are available in a suitable data mass memory 2. For converting the acquired or available data sets of the actual model and the reference model into the data of a CAD free-form surface geometry and for the subsequent manipulation of this data, use is made of a suitably efficient computer 3, which is equipped with a video screen 4 and with the usual digital and/or graphical input unit 5.

The final formation of the difference for generating the computer-internal model for the endoprosthesis to be produced also takes place in the computer 3.

Finally, the endoprosthesis is produced in a computer-controlled manufacturing unit 6.

Fig. 3 shows a printout of a representation of the actual model as it is shown on the video screen 4 in method step C.

Fig. 4 shows the reference model by the same representation.

In Fig. 5, the actual model 10 according to Fig. 3 and the reference model according to Fig. 4 are shown superimposed. In this representation on the video screen 4, the two models are expediently shown in different colours, so that they can be better distinguished from each other. It is possible to place through the two superimposed models any desired sections, on the basis of which the adaptation and the subsequent fine adaptation are made at the critical sites. The adaptation essentially takes place by support point displacement. The fine adaptation takes place by geometric manipulation functions (reflecting, expanding, turning, rounding, smoothing etc.). The adaptation is made in a way

such that the height and position in the direction of the sagittal and transversal planes as well as the recesses of exit regions of the sensitive nerves of the lower jaw are adapted to the shape of the endoprosthesis to be produced. The well-rounded shape and the sweeping curve of the sagittal plane orientation (compensation curve) of the endoprosthesis to be produced are obtained already in advance through the reference model shown in Fig. 4.

A section along line A--A in Fig. 5 is shown in Fig. 6. In the latter figure, for better clarity, the cross section of the actual model 10 with its interface 11, the bone canal 12 and an undercut 13 is shown by dark hatching, whereas the cross section of the reference model 14 is shown by light hatching. Fig. 6 shows that the interface 11 of the actual model 10 has been displaced within the region of the exit 12a of the bone canal 12 and the undercut 13 into the volume of the reference model 14. The cross sectional surfaces of the reference model that have become exposed due to the displacement are not hatched. Following the formation of the difference between the actual model 10 and the reference model 14, recesses or cavities are created within the region of these unhatched areas, in the region of which recesses or cavities, the manufactured endoprosthesis does not rest against the surface of the bone structure of the patient (=actual model).

Claims

1. Method for producing endoprostheses, in particular individually constructed implants and augments for reconstructive head surgery, in which the data set of a three-dimensional actual model of the existing bone structure of a patient is acquired by means of computer tomography, the actual model thus acquired is subtracted in a computer from the data set of an existing or computer tomographically acquired, three-dimensional reference model, and a computer-internal model for the endoprosthesis is formed from the difference of the data sets, this model being adapted on the video screen of the computer by interactive manipulation of the data to the special anatomical features of the patient, and the data set thereof being finally used for the computer-controlled manufacture of the endoprosthesis, characterised in that the data sets of the actual model (10) and of the reference model (14) are converted into the data of a CAD free-form surface geometry describing the limiting surfaces of the models by Spline and Bezier functions oriented to the points of support, and shown as superimposed imaging on the video screen of the computer, and that with the aid of this imaging, part areas of the interface (11) of the actual model (10) are recessed by support point displacement in the direction of the volume of the reference model (14).

2. Method according to claim 1, characterised in that the final shaping and fine adaptation of the new curve of the interface created by the recessing is supported by reflecting, expanding, rounding or smoothing.

3. Method according to claim 1 or 2, characterised in that a high-resolution computer tomograph (1) with helical data collection is used for the data acquisition.

Abstract

Method for producing endoprostheses

The invention relates to a method for producing endoprostheses in which the data set of a three-dimensional actual model (10) of the existing bone structure of a patient is acquired by means of computer tomography, the actual model (10) so determined is subtracted in a computer from the data set of an existing or computer tomographically acquired, three-dimensional reference model (14), and a computer-internal model for the endoprosthesis is formed from the difference of the data sets.

In order to reduce in this method the expenditure of labour required for the corrective adaptation of the endoprosthesis and to avoid faulty adjustments, the invention proposes that the data sets of the actual model (10) and the reference model (14) should be converted into the data of a CAD free-form surface geometry describing the limiting surfaces of the models by a spline and Bezier functions oriented to points of support and are represented on the video screen of the computer lying one on top of the other, and that with the aid of this imaging, part areas of the interface (11) of the actual model (10) are recessed by displacing points of support in the direction of the volume of the reference model (14).